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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,086	11/29/1999	PASCUAL PEREZ	BET-99/0730	2155

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/20/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/380,086

Applicant(s)

PEREZ ET AL.

Examiner

Anne Kublik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16 and 18 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The request filed on 11 July, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/380,086 is acceptable and a CPA has been established. An action on the CPA follows.
2. As requested in Paper No. 23, filed 11 July, 2002, the amendments to claims 13 and 15 have been entered. Claims 13-18 are pending. Claim 17 remains withdrawn from consideration as being drawn to a nonelected invention. Claims 13-16 and 18 are examined.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

4. The rejection of claims 13-16 and 18 under 35 U.S.C. 103(a) as being unpatentable over Paul et al (1992, Plant Mol. Biol. 19:611-622) in view of each of Ellstrand et al (1990, Bioscience 40:438-442) and Nyers et al (1991, J. Cell Biochem 15A:136) is WITHDRAWN as Paul et al do not teach integration of a transgene into a plant that is already male sterile.
5. The rejection of claims 13-16 and 18 under 35 U.S.C. 103(a) as being unpatentable over Worrall et al (1992, Plant Cell 4:759-771) in view of Ellstrand et al and Nyers et al is WITHDRAWN as Worrall et al do not teach integration of a transgene into a plant that is already male sterile.
6. The rejection of claims 13-16 and 18 under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al (US Patent 5,728,558, filed July, 1990) in view of each of Ellstrand et al and

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Nyers et al is WITHDRAWN in favor of the 35 USC 102(e) rejection over Fabijanski et al below.

Claim Rejections - 35 USC § 112

7. Claims 13-16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method for preventing dissemination of a transgene via pollen in a plant that has the transgene, by introducing a transgene into a male sterile plant.

The instant specification, however, only provides guidance for construction of plant transformation vectors comprising a gene conferring male sterility, comprising the A9 promoter operably linked to either the glucanase or the barnase gene, a gene encoding dog gastric lipase, and a gene conferring resistance to Basta (examples 1-2); and transformation of the vectors into *Brassica napus* (example 3) and tobacco (example 4). The instant specification also provides guidance for construction of a plant transformation vectors comprising the Ac transposase gene (example 5) and one presumably comprising the A9 promoter operably linked to the glucanase gene and excision sequences (example 6); transformation of the vector of examples 5 and 6 into separate tomato plants (example 7); constructing a vector comprising a Ds element inserted into the Gus gene, transforming this into plants and showing that the plants produced blue spots, *i.e.*, that the Ds element was excised (example 8); and generation of T2 seeds that contain an unidentified transgene (example 9). The instant specification also provides guidance for crossing

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male sterile plants containing the Ds element and an unknown artificial male sterility gene to plants expressing the Ac transposase (example 10); identification of the excision event in F1 plants by PCR to determine which no longer have the AMS gene - such plants in an unexplained manner also lack the transposase gene but have an undefined gene of interest (example 11); and construction of a plant transformation vectors containing the FLP recombinase (example 12) and the one containing a A9-barnase male sterility gene and a kanamycin resistance gene between FRT recombination sites (example 13).

It is noted that following what exactly was done in the examples and what each vector and plant comprises is very difficult, and in some cases impossible, to determine from the specification.

The instant specification fails to provide guidance for a method for preventing dissemination of a transgene via pollen in a plant that has the transgene, by introducing a transgene into a male sterile plant.

The specification fails, for example, to describe transformation of a male sterile plant with a transgene. It also fails to teach male sterile plants in which the transgene was introduced by crossing - the plants produced in example 12 lack the AMS gene, and as such produce pollen. Thus, the specification fails to provide guidance for any method of introducing a transgene into male sterile plants to produce male sterile plants that cannot transmit the transgene via pollen.

Lastly, the instant specification fails to provide guidance for a method of integrating a transgene linked to an AMS gene into a male sterile plant. The specification fails to provide guidance for a method of transformation to target the transgene to the region of the nuclear genome near the gene responsible for the artificial male sterility. The specification also fails to

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teach transformation of a male sterile plant with a construct comprising a transgene and an artificial male sterility gene.

As the specification does not describe the transformation of any male-sterile plant with a transgene to produce a male sterile plant that has the transgene and that cannot disseminate the transgene via pollen, undue trial and error experimentation would be required to screen through the myriad of transgenes encompassed by the claims and plants transformed therewith, to identify those with that cannot disseminate the transgene via pollen, if such plants are even obtainable.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for preventing dissemination of a transgene via pollen in a plant that has the transgene, by introducing a transgene into a male sterile plant.

8. Claims 13-16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase “plant is cultivated for seed or fruit reduction”. Additionally, neither the instant specification nor the originally filed claims appear to provide support for the phrase “plant is cultivated for ... fruit production” (if “production” was what was actually intended - see 35 USC 112, 2nd paragraph rejection below). Thus, such phrase constitutes NEW MATTER. In response

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to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

9. Claims 13-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 13 is indefinite in its recitation of “rendered male sterile”. It is unclear what is meant by “rendered” - are only plants that are male sterile because their genetic make-up so dictates or are genetically male fertile, but emasculated plants included?

For clarity, --and-- should be inserted before “wherein” in claim 13, line 6.

Claim 13 is indefinite in its recitation of “seed or fruit reduction”. It is not clear what seed or fruit reduction is. Was seed or fruit production intended?

It is not clear what it means for a plant to possess nuclear male sterility. Does this mean the plant has an allele of a nuclear gene that plays a role in male sterility but that male sterility is conferred by another method (*e.g.*, cytoplasmic male sterility or emasculation), or does this mean that the male sterility of the plant used in the method of claim 13 is caused by a nuclear gene (as opposed to a cytoplasmic one)?

Claim 16 lacks antecedent basis for the limitation “said male sterility” in line 3.

Claim 16 is indefinite in its recitation of “artificial male sterility (AMS) gene”. It is unclear what it means for a male sterility gene to be artificial - in what manner is it artificial?

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Claim 16 is indefinite in its recitation of “genetically linked”. Does this mean the AMS gene is on the plasmid vector or does this mean that after transformation, the transgene is linked to the AMS gene (and if so, how is this accomplished?)

In claim 18, it is unclear if a male sterile plant is being transformed with a transgene that is “genetically linked” to an AMS gene or if a non-male sterile plant is being transformed with a transgene that is “genetically linked” to an AMS gene.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Svab et al (1990, Proc. Natl. Acad. Sci. USA 87:8526-8530).

Svab et al teach transformation of a male sterile tobacco plant with a transgene that confers spectinomycin resistance (pg 8526, right column, paragraph 1, and pg 8527, right

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column, paragraph 1). This method would inherently prevent dissemination by pollen, because the plants are male sterile. Tobacco is cultivated for seed production, for example for planting.

12. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Maliga et al (1995, US Patent 5,451,513).

Maliga et al teach transformation of a male sterile tobacco plant with a transgene that confers spectinomycin resistance (column 12, line 63, to column 13, line 4, and column 14, lines 21-31). This method would inherently prevent dissemination by pollen, because the plants are male sterile. Tobacco is cultivated for seed production, for example for planting.

13. Claims 13-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgensen (1993, US Patent 5,180,873).

Jorgensen teaches a method of introducing a transgene (for example, a kanamycin resistance gene) into a plant by transformation with a transgene (column 16, line 1, to column 18, line 68; column 19, line 40, to column 23, line 8; claims 1-40), wherein the plant is maize, rapeseed or tomato (column 7, lines 45-62; column 17, lines 7-28; and column 19, line 40, to column 23, line 8, claim 19). The transformants are male sterile and contain the transgene. The male sterility would "artificial" because it is caused by mutation. This method is one where the transgene is genetically linked to the male sterility gene (column 22, lines 40, to column 23, line 8; claims 1-40). This method would inherently be one for preventing dissemination of a transgene via pollen because the transformed male sterile plants would not be able to produce pollen (column 18, lines 57-68) and thus, the transgene could not be disseminated by pollen.

14. Claims 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mariani et al (US Patent 5,689,041, filed March, 1991).

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Mariani et al teaches a method of integrating a transgene (pMP90, which has a kanamycin resistance gene on it among others) into a male sterile tobacco and rape plants by crossing the plants transformed with pMP90 with the male sterile plant (column 27, line 55, to column 28, line 19). Some of the resulting progeny, which would have the transgene because they survived selection on kanamycin, are male sterile (column 28, lines 16-19). This method would inherently be one for preventing dissemination of a transgene via pollen because the transformed male sterile plants would not be able to produce pollen, and thus, the transgene could not be disseminated by pollen.

15. Claims 13-16 are rejected under 35 U.S.C. 102(e) as being unpatentable over Fabijanski et al (US Patent 5,728,558, filed July, 1990).

The claims are drawn to a method for preventing transgene dissemination via pollen by integrating a transgene into a male sterile plant.

Fabijanski et al teach a method of producing male sterile plants and sequential transformation of those plants with another transgene or crossing those male-sterile plants with another plant that has been transformed with a transgene (column 25, lines 20-39, and column 32, lines 23-62). The male sterility gene would be nuclear, because it is transformed into the nucleus, and it would be artificial; the plants are made male-sterile by transformation with a nucleic acid that encodes a protein that converts IAM to toxic levels of IAA (column 32, lines 56-62). This method would inherently be one for preventing dissemination of a transgene via pollen because the transformed male sterile plants would not be able to produce pollen, and thus, the transgene could not be disseminated by pollen.

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Applicant's arguments filed 11 July, 2002, in response to a 35 U.S.C. 103(a) of these claims as being unpatentable over Fabijanski et al in view of each of Ellstrand et al and Nyers et al has been fully considered but they are not persuasive. Applicant urges that Fabijanski et al do not teach using the plants to prevent transgene escape (response pg 3). This is not found persuasive because prevention of transgene escape would be an inherent property of these plants because they cannot produce pollen.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Sonya Williams, at (703) 305-2272.

Anne R. Kubelik, Ph.D.
September 13, 2002



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